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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/914,340	02/19/2002	Hidekazu Shodai	YAM 2 0009	3665

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Richard M Klein
Fay Sharpe Fagan Minnich & McKee
1100 Superior Avenue Seventh Floor
Cleveland, OH 44114

EXAMINER	
TRAN, SUSAN T	

ART UNIT	PAPER NUMBER
1615	

DATE MAILED: 11/30/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/914,340	SHODAI ET AL.	
	Examiner	Art Unit	
	Susan T. Tran	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11 September 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2,4-8 and 10-34* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2,4-8 and 10-34* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 10 and 31-33 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 10 is rejected for failing to further limit the subject matter of claim 1. Applicant is required to cancel the claim, or amend the claim to place it in proper dependent form, or rewrite the claim in independent form. Claim 1 recited the chocolate base comprising cocoa butter.

Claims 31-33 are rejected for failing to further limit the subject matter of claim 8. Applicant is required to cancel the claim, or amend the claim to place it in proper dependent form, or rewrite the claim in independent form. Claim 8 already recited the phrase "further comprising". The phrase "further comprising" in claims 31-33 is confusing.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 8, 24 and 26 are rejected under 35 U.S.C. 102(b) as being anticipated by Damour et al. US 5,563,144.

Damour discloses a capsule containing in addition to the active product, excipients such as cacao butter, glycerides or polyethylene glycol (column 12, lines 61-64). Active agent includes analgesic (column 3, lines 40-41).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1, 2, 4-7, 10-17 and 19-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Liu et al. US 4,576,826, in view of Borkan et al. US 4,935,243.

Liu discloses a process for the preparation of flavorant capsule comprising obtaining a stable fill comprises tea, coffee, chocolate, and other flavor and/or aromatic principles, both natural and/or artificial (abstract; column 2, lines 5-32; and column 3, lines 13-23). Liu further discloses the fill is kept under an advantageous temperature ranges from 0°C to 40°C (column 4, lines 11-20). Liu also discloses the obtained capsules are dried at room temperature over a period of time (column 6, lines 15-22).

Liu does not explicitly teach the soft capsule shell.

Borkan teaches a chewable, edible soft gelatin capsule comprising a solid or semi-solid fill material (see abstract; and column 3, lines 1-5). The gelatin shell

comprises gelatin, glycerin as a plasticizer, D-sorbitol, and sweetener (columns 3-4; and column 5, lines 1-36). Thus, it would have been obvious for one of ordinary skill in the art to use the chewable, edible soft gelatin capsule of Borkan to encapsulate the fill material of Liu, because Borkan teaches capsule shell that is dispersible and soluble in the mouth of the user (abstract), and because Liu teaches capsule shell that is able to readily dissolve in cold and hot water (column 5, lines 1-5).

Claims 1, 2, 4-8, 10-17 and 19-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nitardy US 2,206,113, in view of Ebert et al. US 4,532,126.

Nitardy teaches a composition comprising therapeutic agent, and melted fat filled into capsules to be chewed and swallowed (column 1, lines 1-15; and column 2, lines 13-16). Melted fat includes coconut oil, and cacao butter (column 1, lines 16-33; and examples). Nitardy further teaches the melted fat is permitted to cool over a period of time to permit evaporation of solvent, and to obtain a solid mass (examples).

Nitardi does not expressly teach aging the fill material.

Ebert teaches drying the freshly made capsule for a suitable length of time until the desired chewing characteristics are attained (see abstract; column 2, lines 46-54; column 4, lines 37-41; and examples). Ebert does not explicitly teach the drying temperature at 30 to 40°C. However, drying can be at room temperature which falls within the claimed range, see Sacripante at column 7, lines 66-67, which teaches room temperature is from about 20°C to about 40°C; or Takegawa at page 2, lines 24-25, which teaches room temperature is in a range of 0°C to 40°C. Ebert teaches a

chewable soft gelatin capsule comprising gelatin, water, a plasticizer and a masticatory substance (Col. 54-68). The plasticizer is glycerin or sorbitol (Col. 2, lines 54-60). The capsule is filled with candy confectionaries, antacids, cough preparations, cold preparations, sore throat remedies, antiseptics, dental preparations, dextromethorphan, and/or acetaminophen (Col. 3, line 67 - Col. 4, line 3; Col, 5; Example 11; Col. 6, Example IV). The capsules also contain taste modifiers or flavoring agents (Col. 4,lines 1 3-25). Thus, it would have been obvious to one of ordinary skill in the art to dry the capsule taught by Nitardy in view of the teaching of Ebert, because Ebert teaches capsules are dried to obtain a desired chewing characteristics (id), and because Nitardy teaches cooling the melted fat to obtain a solid fill suitable for chewable capsule.

Claims 31-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nitardy, in view of Perry et al. EP 0 904 064 and Miyake et al. US 4,219,439.

Nitardy does not expressly teach the claimed filled material.

Perry teaches an oral pharmaceutical composition to be filled into capsules comprising digestible oil in the carrier including coconut oil, polyethylene glycol, and surfactant such as castor oil (paragraphs 0019-0020). Miyake teaches oil includes lard, castor, soybean, combination thereof, and the like (column 4, lines 3-10). Thus, it would have been obvious to one of ordinary skill in the art to modify the composition of Nitardy using the additives in view of the teachings of Perry and Miyake, because Perry teaches the use of digestible oil to provide good solubilisation to employ a smaller capsule size

to deliver the same drug doses compared with similar formulations in the prior art, and because Miyake teaches the equivalency between lard and other digestible oils.

Claim 18 is rejected under 35 U.S.C. 103(a) as being unpatentable over Nitardy in view of Mehta US 5,084,278.

Nitardy does not teach the flavoring agent such as chocolate flavor.

Mehta teaches a chewable taste mask capsule comprising a fill composition containing sweetening agent, and flavoring agent includes chocolate flavor (column 9, lines 46 through column 10, lines 1-15). Thus, it would have been obvious for one of ordinary skill in the art to use chocolate flavor as the flavoring agent for the fill material taught by Nitardy, because the references teach compositions suitable for chewable composition.

Response to Arguments

Applicant's arguments filed 09/11/06 have been fully considered but they are not persuasive.

Applicant argues that Damour does not teach chewable capsule. In response to applicant's argument that the reference fails to show certain features of applicant's invention, it is noted that the feature upon which applicant relies (i.e., chewable capsule) is not recited in the rejected claims. Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

Applicant argues that Ebert discloses the capsule is dried, not the fill material. Applicant further emphasized that the step of aging the fill material is distinct from the step of drying the capsule, and the specification describes both steps separately. In response to applicant's argument, the examiner is unable to determine the distinct between the two steps. Applicant's attention is called to the instant specification at pages 19-20, which describes *the process of production of the soft capsule of the present invention comprising melting the chocolate base, mixing drug (or food) and other excipients to the melted chocolate base while heating to obtain a fill material as a uniform suspension. Separately a shell material is prepared, and the shell is filled with the fill material. After filling the capsule, optionally followed by drying in a drying chamber whose temperature is controlled. This drying step is continued at a desired temperature for a predetermined time or more so that the fill material can experience an aging effect*. Accordingly, the teaching of drying the filled capsule in Ebert would be inherent and obvious the claimed aging step.

Applicant argues that the teaching of Borkan, Ebert, and Mehta that the capsules have superior taste does not mean they achieve their superior taste in the same way as the instant application. This statement has not been supported by any Declaration showing that the superior taste taught by the cited references is detrimentally different from the claimed invention.

Applicant argues that Liu does not teach the claimed temperature, which is at 30-40°C. Contrary to the applicant's argument, Liu at column 4, lines 11-18, teaches

advantageous temperatures that are to be employed during the preparation of the emulsion and during it storage are within 30°C to 40°C.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan T. Tran whose telephone number is (571) 272-0606. The examiner can normally be reached on Monday through Thursday 6:00 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (571) 272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

S. Tran
Patent Examiner
Art Unit 1615